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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,879	05/25/2001	Igor B. Roninson	99,216-H	5092

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/08/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/865,879

Applicant(s)

RONINSON ET AL.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-11 is/are allowed.
- 6) ☒ Claim(s) 12-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-26-2003 has been entered. Claims 8-18 are pending and examined on merits.

Information Disclosure Statement

Only the abstract of EP 0280135A, a copy of the IDS filed on 4-28-2003 has been considered because the patent is not in the English language.

Claim Rejections - 35 USC § 102

The rejection of claims 8-11 under 35 U.S.C. 102(b) as being anticipated by Simon et al (IDS, 1996, Cancer Research, vol. 56, pages 5369-74) as evidenced by Montemurro et al (1999, British Journal of Haematology, vol. 107, pages 294-299, abstract only) is **withdrawn** because applicant argument is persuasive.

The rejection of claims 8-12, 14, 16, and 18 under 35 U.S.C. 102(b) as being anticipated by WO 96/23080 (IDS filed on 7-10-2002) is **withdrawn** because applicant's argument, that the WO 96/23080 does not contemplate identifying non-retinoids using the retinoid-inducible assay system, is persuasive.

The rejection of claims 12-18 under 35 U.S.C. 102(b) as being anticipated by either Hembree et al (IDS filed on 7-10-2002, and Cancer Research vol. 56, pages

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1793-9) or Shang et al (IDS filed on 7-10-2002) is **withdrawn** because all of the compounds tested are retinoids.

Claim Rejections - 35 USC § 103

The rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over Adamo et al (1992, Endocrinology 131:1858-1866), Miller (1998, Cancer 83: 1471-82), Han et al (1997, J. Biol. Chem. 272: 13711-13716), and US Pat. 5,795,726 (18 Aug.1998), is **withdrawn** because applicant argument is persuasive.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12, 13, and 15 recite "gene" but it is not clear what the metes and bounds are for the limitation because it appears claim 13 defines "gene" as a promoter region, for example instant SEQ ID NO:2 in claim 13 appear to be the promoter of secreted cell adhesion protein β G-H3, excluding the protein coding sequence. However, claim 15 appears to define the secreted cell adhesion protein β G-H3 to be more than the promoter sequence defined in claim 13. Further claim 16 appears to be drawn to detect a protein encoded by a gene using immunological reagent. Darnell et al (Molecular Cell

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Biology, 1990, W. H. Freeman and Company, page 344 only) teach that "gene" is more than promoter and coding sequence.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is based on the Office interpretation of the claim is drawn method of screening useful compounds by detecting an activity of β G-H3 (the elected species). Neither the specification nor the art, for example, Skonier et al (cited below) or Kim et al, Oncogene. 2003 Apr 3;22(13):2045-53, teaches that β G-H3 protein has an assayable activity in screening useful compound. For example, if the apoptosis assay of Kim et al (cited above) is used in the instantly claimed method, it would be difficult to tell whether a test compound causing apoptosis of a mammalian cell is through β G-H3 or some other signaling systems. The protein does not appear to be enzyme or to possess an activity could be assayed in the claimed screening method. The current of state art teaches that the protein is involved in complicated signaling and it appears to be difficult for assaying an activity of the particular protein in screening method. Considering the state of art, lack of working example and limited guidance in the specification, it is concluded that undue experimentation is required to practice the invention.

Claim Rejections - 35 USC § 102

Claims 12, 14, 15, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Skonier et al (1992, IDS, DNA and Cell Biology, vol. 11, pages 511-522).

The claim is interpreted as drawn to method of screening a non-retinoid compound by detecting higher expression of retinoid-inducible gene expression (β G-H3, the elected species) in presence of said compound. Skonier et al teach at Fig. 1 A that culturing mammalian cell (A549 cells) in presence of TCF- β 1 (a non-retinoid compound), assaying the cells for changes in expression of β G-H3, and detect the higher β G-H3 expression in presence of TCF- β 1, and identify TCF- β 1 as inducer of β G-H3. Although the authors of the publication did not know the β G-H3 promoter is inducible by retinoid, the nature of β G-H3 promoter is the inherent property of the promoter without any manipulation of the inventors' of the instant application. Thus, it is the Office's position that the prior art anticipates instant claim.

Claim Rejections - 35 USC § 103

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Skonier et al (cited above).

The claim is interpreted as drawn to the screening method using expression of the protein as the detection step. The art teaches that antibody directed to the protein is made at Fig. 9. Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to detect protein expression in the screening method with reasonable expectation of success.

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Allowable Subject Matter

Claims 8-11 are allowed.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
September 2, 2003


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800-1600